

**EXHIBIT G**  
**AMENDMENT (09/18/01)**

1103326-0502**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants : Cotton et al.  
Serial No. : 09/077,719  
Filed : June 8, 1998  
For : NOVEL FORM OF S-OMEPRAZOLE  
Examiner : J. Fan  
Group Art Unit : 1625

<b>CERTIFICATE OF TRANSMISSION UNDER 37 CFR §1.8</b>	
I hereby certify that this paper is being transmitted by facsimile to the Assistant Commissioner for Patents Washington, D.C. 20231, on September 18, 2001.	
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<u>John M. Genova</u> Signature	<u>18 September 2001</u> Date of Signature

**ATTENTION: Examiner Jane Fan****GROUP ART UNIT: 1625****NUMBER OF PAGES: 8****FAX NUMBER: 703-308-4734**

Assistant Commissioner for Patents  
Washington, D.C. 20231

**AMENDMENT UNDER 37 C.F.R. §1.111**

Sir:

Applicants submit this Amendment in response to the Office Action, mailed July 5, 2001.

**IN THE CLAIMS:**

**Cancel claims 3 and 18 without prejudice.**

**Substitute the following amended claims 1, 4, 5, 9, 14 and 16 for pending claims 1, 4, 5, 9, 14 and 16, respectively:**

1. (Amended) The magnesium salt of S-omeprazole trihydrate, wherein the compound is characterized by the following major peaks in its X-ray diffractogram:

d-value / Å	Relative Intensity
2.67	m
2.79	m
3.27	m
3.52	s
3.82	s
3.96	vs
4.14	m
5.2	m
5.6	m
6.7	vs
6.9	s
8.3	w
16.6	vs

4. (Amended) A process for the preparation of the magnesium salt of S-omeprazole trihydrate according to any of claims 1, 2 or 17 which comprises treating a magnesium salt of S-omeprazole of any other form with water.

5. (Amended) A process for the preparation of the magnesium salt of S-omeprazole trihydrate according to any of claims 1, 2 or 17 which comprises the following steps:

- a) mixing a potassium salt of S-omeprazole with an organic solvent;
- b) converting the potassium salt of S-omeprazole into a corresponding magnesium salt of S-omeprazole by treating the potassium salt with a magnesium source;
- c) precipitating the magnesium salt of S-omeprazole by addition of a non-solvent;
- d) isolating the obtained magnesium salt of S-omeprazole;
- e) treating the obtained magnesium salt of S-omeprazole with water; and
- f) isolating and drying the obtained magnesium salt of S-omeprazole trihydrate.

9. (Twice amended) The process according to claim 5, wherein the magnesium source is magnesium sulfate.

14. (Twice amended) A pharmaceutical composition comprising the magnesium salt of S-omeprazole trihydrate according to any of claims 1, 2 or 17 as active ingredient and a pharmaceutically acceptable carrier.

16. (Twice amended) A method of treating a gastric acid related condition which method comprises administering to a subject suffering from said condition a therapeutically effective amount of the magnesium salt of S-omeprazole trihydrate according to any of claims 1, 2 or 17.

**Add new claim 19:**

19. The process according to claim 8, wherein the magnesium source is magnesium sulfate.

**REMARKS****I. Claim Amendments**

Claim 1 has been amended to incorporate the embodiment of claim 3 and, therefore, claim 3 has been canceled. Claims 4, 5, 14 and 16 have been amended to correct the recitation of claims from which they depend. Claim 9 has been amended to remove an indirect improper multiple dependency. Claim 18 has been canceled. New claim 19 is directed to the embodiment eliminated from amended claim 9.

Applicants submit that no new matter has been introduced by any the claim amendments.

**II. Restriction Requirement**

In response to the restriction requirement of record, Applicants elected the inventions of Groups I and II (claims 1-4, 14, 16 and 17) and canceled claims 10-13 of Groups IV and V. The restriction requirement as to Group VI (claim 18) was made final.

In Paragraph 1 of the Office Action, the Examiner has indicated that the invention of Group III (process claims 5-9) would be rejoined in the event that the claimed product is allowed. In Paragraph 8 of the Office Action, claim 3 is objected to as being dependent upon a rejected base claim, but would be allowable if re-written in independent form including all of the limitations of the base claim and any intervening claims. Claim 1 has been amended in the manner suggested by the Examiner. Accordingly, it is submitted that the claimed product is allowable and, therefore, it is requested that the restriction requirement as to the invention of Group III (process claims 5-9) be withdrawn and that claims 5-9 be rejoined in the present application.

### **III. Claim Rejections**

For all of the foregoing reasons, Applicants respectfully submit that claims 1, 2, 4-9, 14, 16, 17 and 19 are in condition for allowance.

In Paragraph 3 of the Office Action, claims 1, 2, 4, 14, 16 and 17 are rejected under 35 U.S.C. §103(a) as being unpatentable over the prior art of record for the reasons of record. The Examiner has noted that the Declaration of Frans W. Langkilde, which was submitted concurrently with Applicants' communication of April 26, 2001, is only relevant to the claimed compound having the X-ray powder diffractogram values as recited in claim 3. Incorporation of the embodiment of claim 3 into claim would overcome the rejection. Claim 1 has been amended in the manner suggested by the Examiner. Accordingly, withdrawal of the rejection under 35 U.S.C. §103(a) is requested.

In Paragraph 4 of the Office Action, claims 1, 2, 4, 14, 16 and 17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the patents of record for the reasons of record. Withdrawal of the rejection is requested in view of amended claim 1.

In Paragraph 5 of the Office Action, claims 1, 2, 4, 14, 16 and 17 are provisionally rejected under 35 U.S.C. §103(a) as being unpatentable over co-pending patent application serial No. 09/690,044 (the "'044 application"). In Paragraph 7 of the Office Action, claims 1, 2, 4, 16 and 17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of the co-pending '044 application. Applicants respectfully submit that the provisional rejections in view of the '044 application are moot due to the amendment of claim 1. Accordingly, withdrawal of the provisional claim rejections is requested.

**IV. Mark-up of amended claims showing insertions and deletions:**

1. (Amended) The magnesium salt of S-omeprazole trihydrate, wherein the compound is characterized by the following major peaks in its X-ray diffractogram:

d-value / Å	Relative Intensity
2.67	m
2.79	m
3.27	m
3.52	s
3.82	s
3.96	vs
4.14	m
5.2	m
5.6	m
6.7	vs
6.9	s
8.3	w
16.6	vs

4. (Amended) A process for the preparation of the magnesium salt of S-omeprazole trihydrate according to any of claims 1, 2 [1-3] or 17 which comprises treating a magnesium salt of S-omeprazole of any other form with water.
5. (Amended) A process for the preparation of the magnesium salt of S-omeprazole trihydrate according to any of claims 1, 2 [1-3] or 17 which comprises the following steps:
- mixing a potassium salt of S-omeprazole with an organic solvent;
  - converting the potassium salt of S-omeprazole into a corresponding magnesium salt of S-omeprazole by treating the potassium salt with a magnesium source;
  - precipitating the magnesium salt of S-omeprazole by addition of a non-solvent;

- d) isolating the obtained magnesium salt of S-omeprazole;
- e) treating the obtained magnesium salt of S-omeprazole with water; and
- f) isolating and drying the obtained magnesium salt of S-omeprazole trihydrate.

9. (Twice amended) The process according to claim 5 [or 8], wherein the magnesium source is magnesium sulfate.

14. (Twice amended) A pharmaceutical composition comprising the magnesium salt of S-omeprazole trihydrate according to any of claims 1, 2 [1-3] or 17 as active ingredient and a pharmaceutically acceptable carrier.

16. (Twice amended) A method of treating a gastric acid related condition which method comprises administering to a subject suffering from said condition a therapeutically effective amount of the magnesium salt of S-omeprazole trihydrate according to any of claims 1, 2 [1-3] or 17.



**CONCLUSIONS**

Applicants respectfully submit that the claim amendments and Remarks are fully responsive to the outstanding Office Action. Claims 1, 2, 4-9, 14, 16, 17 and 19 are in condition for allowance, which action is earnestly solicited.

Any additional fees due in connection with Preliminary Amendment should be charged to Deposit Account No. 23-1703.

Dated: 18 September 2001

Respectfully submitted,



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